DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 8, 2015

Rhythmia Medical, Inc
Frank Jurczak
Manager, Regulatory Affairs
111 South Bedford St Suite 205
Burlington, Massachusetts 01803

Re: K143481
Trade/Device Name: IntellaMap Orion High Resolution Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: December 5, 2014
Received: December 9, 2014

Dear Frank Jurczak,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K143481

Device Name: IntellaMap Orion™ High Resolution Mapping Catheter

Indications for Use: The IntellaMap Orion™ High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

Prescription Use _X AND/OR Over-The-Counter Use_____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary of Safety and Effectiveness

Rhythmia Medical, Inc.

IntellaMap Orion™ High Resolution Mapping Catheter

General Information

Date Compiled December 5, 2014

Classification Class II, 21 CFR § 870.1220, Electrode Recording Catheter or Electrode Recording Probe, Product Code DRF (Catheter, Electrode Recording, or Probe, Electrode Recording)

Trade Name IntellaMap Orion™ High Resolution Mapping Catheter

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Indications for Use

The IntellaMap Orion™ High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

Predicate Device

Rhythmia Mapping Catheter, K122461, Manufactured by Rhythmia Medical, Inc.

Product Description

The IntellaMap Orion™ High Resolution Mapping Catheter is intended for multiple electrode electrophysiology mapping of the heart and is intended for recording of electrograms and stimulation of cardiac tissue. The IntellaMap Orion™ High Resolution Mapping Catheter is a 8.5 French (2.8mm), 115 cm, bidirectional, 64 electrode, non-linear (basket shaped) diagnostic catheter. The catheter consists of a polymer handle, a polymer shaft and a platinum/iridium and polymer distal mapping section mounted with iridium electrodes ('electrode array'). The catheter contains a flushing port capable of providing continuous flushing into the electrode array. The catheter is

supplied with an 8.5 French insertion sleeve for insertion through the hemostasis valve of an introducer sheath. The catheter is provided sterile and is for single use only.

The IntellaMap Orion™ High Resolution Mapping Catheter simultaneously acquires 64 electrograms from the electrodes on its splines. The catheter is designed to enter the vasculature with a low profile (8.5F) through a percutaneous approach. The catheter can be maneuvered with the aid of a handle that controls bidirectional steering and array deployment.

Determination of Substantial Equivalence

Rhythmia Medical believes the proposed modification to the handle of the IntellaMap Orion™ High Resolution Mapping Catheter does not impact the device's substantial equivalence to the previously cleared version of this device and is as safe, as effective, and performs as well as the predicate device. The indications for use, intended use, product function, design and materials used, are either identical or substantially equivalent to previously cleared IntellaMap Orion™ High Resolution Mapping Catheter (formerly Rhythmia Mapping Catheter) predicate device.

Conclusion

The proposed IntellaMap Orion™ High Resolution Mapping Catheter is equivalent in indications for use, intended use, product function, design and materials to the predicate device, the IntellaMap Orion™ High Resolution Mapping Catheter (formerly Rhythmia Mapping Catheter cleared in K122461).

Because of the similarities of indications for use, intended use, product function, design and materials, and verification testing, Rhythmia Medical, Inc. believes the IntellaMap Orion™ High Resolution Mapping Catheter to be substantially equivalent to the predicate device, the IntellaMap Orion™ High Resolution Mapping Catheter (formerly Rhythmia Mapping Catheter cleared in K122461).

Summary of Non-Clinical Performance Data

Non Clinical performance of the modified IntellaMap Orion™ High Resolution Mapping Catheter has been fully evaluated based upon bench top testing referenced within this submission. The verification testing confirmed that the new handle design met the product performance requirements of the predicate device. Based on this result, the modified device can be considered substantially equivalent to the predicate.